PATENT ATTORNEY DOCKET NO. 00786/206002

THE UNITED STATES PATENT AND TRADEMARK OFFICE

Frederick M. BOYCE

Art Unit:

Serial No.: 08/752,032

Examiner:

Filed

: November 19, 1996

Title

: USE OF A BACULOVIRUS TO EXPRESS AN EXOGENOUS GENE IN

A MAMMALIAN CELL

Assistant Commissioner of Patents Washington, DC 20231

RECEIVED MAR 0 4 1997.

INFORMATION DISCLOSURE STATEMENT

GROUP 1800

Applicant submits the references listed on the attached form PTO 1449.

Under 35 USC 120, this application claims priority from application Serial No. 08/311,157, filed on September 23, 1994. The references listed on the attached PTO Form 1449 were submitted to and/or cited by the Office on the prior application and, therefore, are not provided in this application.

This statement is being filed before the mailing date of a first Office action on the merits. Please apply any charges or credits to Deposit Account No. 06-1050, Reference No. 00786/206002.

Respectfully submitted,

Date: February 26, 1997

Eldora L. Ellison,

Req. No. 39,967

Fish & Richardson P.C. 601 13th Street NW Washington, D.C. 20005

Telephone: 202/783-5070 Facsimile: 202/783-2331

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7	AB	4 8 7 9 2 3 6 11/07/19	89 Smith et al.		435	235				
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B1_	AD	HO 1957238661 09/1995	PCT							
		OTHER DOCUMENTS (In	cluding Author, Ti	tle, Date, Place of Publica	tion)					
		Ashwell G. et al.; "Carbo	hydrate-Specific R	eceptors of the Liver"; Ann	. Rev. Bio	chem. 51:531	1-54 (198	2)		
BL	AE									
		Blissard G.W. et al.; "Baculovirus Diversity and Molecular Biology"; Annu. Rev. Entomol. 35:127-55 (1990)								
1	AF									
		Blissard G.W. et al.; "Baculovirus gp64 Envelope Glycoprotein Is Sufficient To Mediate pH-Dependent Membra						Membra		
	AG	Fusion"; J. of Virology 66:6829-6835 (1992)								
		Burhans W.C. et al.; "DNA	Replication Origi	ns in Animal-Cells:A Questio	on of Conte	ext?"; <u>Scier</u>	<u>nce</u> 263:6	39-640		
	AH	(1994)			. 1,2, , 73			-		
		Burns J.C. et al.; "Vesicu	ular Stomatitis Vi	rus G Glycoprotein Pseudotyp	ped Retrovi	ral Vectors	:Concent	ration		
1	AI	to Very High Titer and Eff	ficient Gene Trans	fer into"; Proc. Natl. A	."; Proc. Natl. Acad. Sci. USA; 90:8033-8037 (1993)					
		Carbonell L.F. et al.; "Ba	aculovirus-Mediate	d Expression of Bacterial Ge	enes in Dip	oteran and M	ammalian	Cells		
	AJ	Journal of Virology, 56:15	53-160 (1985)							
		Carbonell L.F. et al.; "Ba	aculovirus Interac	tion with Nontarget Organism	ns:A Virus-	Borne Repor	ter Gene	Is No		
	AK	Expressed in Two Mammalian	n Cell Lines"; App	lied and Environmental Micro	biology 53	:1412-1417	(1987)			
		Charreau B. et al; "Establ	ishment of Porcing	e Cell Lines Producing a Mur	ine Recomb	inant Retro	virus in	Order		
	AL	to Transfer the nlslacZ Ge	ene into Porcine Co	ells"; <u>Res. Virol.</u> 142:343-3	51 (1991)					
		Cotten M. et al.; "Recepto	or-Mediated Transpo	ort of DNA into Eukaryotic C	ells"; Aca	demic Press	, Inc.			
	AM -	217:618-644 (1993)								
		Cristiano R.J. et al.; "Hepatic Gene Therapy:Adenovirus Enhancement of Receptor-Mediated Gene Delivery and								
	AN	Expression in Primary Hepa	tocytes"; Proc. Na	atl. Acad. Sci. USA 90:2122-	2126 (1993)				
		Demarquoy J.; "Retroviral-	Mediated Gene The	rapy for the Treatment of Ci	trullinemi	a. Transfe	r and Exp	pressio		
-	AO	of Argininosuccinate Synth	etase in Human Her	natopoietic Cells"; <u>Experien</u>	tia 49:345	-348 (1993)				
EXAMINE	R	3 laure	er	DATE CONSIDERED	12/22	/52				
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0.			1 4 4 5 4 1 1 1 1 1 1 1 1 1			Function in Rats			of Microcar	rier-Att	ached
150	ВС		Hepatocytes"; Sci	ence 233:119	90-1192 (1986)						
1			Grompe M. et al.;	"Gene Thera	apy in Man and M	lice:Adenosine Deam	minase Defic	iency, (Ornithine T	anscarba	amylase
	BD		Deficiency, and D	uchenne Musc	cular Dystrophy	; Adv. in Experime	ental Medici	ne & Bio	ology 309B:5	51-56 (19	791)
	BE		Grompe M. et al.;	"Retrovira	l-Mediated Gene	Transfer of Human	Ornithine T	ranscarl	bamylase int	to Primar	У
	DE		Hepatocytes of sp	of and spf-as	sh Mice"; <u>Human</u>	Gene Therapy 3:35	-44 (1992)				·
	BF		Groner, et. al; "	Interaction	of Autographa	alifornica Nuclear	r Polyhedros	is Viru	s with Two M	lonpermis	sive Cel
	Br		Lines"; <u>Interviro</u>	logy 21:203	-209 (1984)				-		
	BG		Hartig P.C. et al	.; "Insect \	/irus:Assays for	Toxic Effects and	d Transforma	tion Po	tential in M	lammaliar	Cells";
	BG		Applied and Envio	ornmental Mic	robiology 55:19	916-1920 (1989)					
	вн		Hartig P.C. et al	.; "Insect \	/irus:Assays for	Viral Replication	and Persis	tence in	n Mammalian	Cells";	
	DIII		J. Virological Me	thods 31:335	5-344 (1991)						
	ВІ		Hata A. et al.;	Structure of	f the Human Orni	thine Transcarbamy	/lase Gene";	J. Bio	chem (Tokyo)	103:302	2-308
	<u>.</u>										
	BJ		Hodges P.E. et al	.; "The spf	sh Mouse:A Misse	nse Mutation in th	ne Ornithine	Transca	arbamylase G	ene Also	Causes
			Aberrant mRNA Spl	icing"; <u>Prod</u>	. Nati. Acad. S	Sci. USA 86:4142-41	146 (1989)				
	ВК		Horwich A.L.; "In	herited Hepa	atic Enzyme Defe	ects as Candidates	for Liver-D	irected	Gene Therap	y"; <u>Curr</u>	<u>ent</u>
			Topics in Microbi	ology and In	munology 168:18	35-200 (1991)					
			Jones S.N. et al.	; "Ectopic (Correction of Or	nithine Transcarba	amylase Defi	ciency	in Sparse Fu	ır Mice";	

DATE CONSIDERED EXAMINER EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Jung, et al.; "A Novel β -Galactoside-Binding Lectin in Adult Rat Kidney"; <u>J. Biochem.</u> 116:547-553 (1994)

Kasahara, et al.; "Tissue-Specific Targeting of Retroviral Vectors Through Ligand -Receptor Interactions";

J. Biological Chemistry 265:14684-14690 (1990)

Science 266:1373-1376 (1994)

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BC	CC		Elsevier Science	Publishers 3	374-377 (1991)						,
1			Maestri N.E. et	al.; "Prospec	tive Treatment	of Urea Cycle Disc	orders"; <u>J. of</u>	Pediatr	rics 119:9	23-928 (1991)
	CD						· · · · · · ·				
			McGrane M.M. et	al.; "Metabol	ic Control of G	ene Expression:In	Vivo Studies W	ith Tra	ansgenic M	ice"; <u>El</u>	sevier
	CE		Science Publishe	<u>rs</u> 17:40-44 (1992)						
	CF		Midoux P. et al.	; "Specific G	ene Transfer Me	diated by Lactosy	lated Poly-L-Ly	sine ir	nto Hepato	ma Cells	";
	ur.		Nucleic Acids Re	search 21:871	-878 (1993)	-	=				
	cc		Mulligan R.C.; "	The Basic Sci	ence of Gene Th	erapy"; <u>Science</u> 20	50:926-932 (199	3)			:
	CG			. *-				, <u>0</u> , 7			
	СН		Shen R. et al.;	"Tissue-Speci	fic Regulation	of Human $lpha_1$ -Antitr	ypsin Gene Exp	ression	in Transo	enic Mic	:e";
	LII		DNA 8:101-108 (19	989)							
	CI		Shimada T. et al	.; "Correctio	n of Ornithine	Transcarbamylase ((OTC) Deficienc	y in sp	of-ash Mic	e by Inti	roduction
	<u> </u>		of Rat OTC Gene"; Elsevier Science Publishers 279:198-200 (1991)								
	СН		Spiess, Martin; "The Asialoglycoprotein Receptor: A Model for Endocytic Transport Receptors"; Biochemistry								
	Cii		29:10009-10018 (1990)							
	CK		Stratford-Perrica	audet et al.;	"Evaluation of	the Transfer and	Expression in	Mice of	an Enzym	e-Encodia	ng Gene
	CK		Using a Human Add	enovirus Vect	or"; <u>Human Gene</u>	Therapy 1:241-256	(1990)				
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		PEN	12/11	pecific and F	Position-Effect	Expression of a Re	tinol-Bino	ling Prote	ein-lacZ Fus	ion Gene	(RBP-	
BC	DC		lacZ) in Transgenic Mice"; Developmental Biology 146:24-37 (1991)									
			Volkman, et al.;	"In Vitro St	urvey of Autogra	apha californica Nu	clear Poly	hedrosis	Virus Inter	action w	ith	
	DD		Nontarget Vetebra	ite Host Cell	s" <u>Applied and</u>	Environmental Micro	obiology 4	5:1085-10	093 (1983)			
	5-		Wagner E. et al.;	"Transferri	n-Polycation Co	onjugates as Carrie	rs for DNA	Uptake i	into Cells";	Proc. N	atl.	
1	DE		Acad. Sci. USA 87	7:3410-3414	(1990)							
	DF		Wilson J.M. et al	.; "A Novel	Mechanism for A	Achieving Transgene	Persister	ce in Viv	o After Son	natic Gen	e	
	Dr		Transfer into Hep	patocytes"; .	Journal of Biolo	ogical Chemistry 26	7:11483-11	489 (1992	?)			
	DG		Wilson J.M. et al	.; "Hepatocy	te-Directed Ger	ne Transfer In Vivo	Leads to	Transient	Improvemen	nt of		
	DG		Hypercholesterole	emia in Low D	ensity Lipoprot	ein"; <u>J. Biol.</u>	Chemistry	267:963-	967 (1992)			
	DH		Wu G.Y. et al.; "	Evidence for	Targeted Gene	Delivery to Hep G2	Hepatoma	Cells in	Vitro"; <u>Bic</u>	chemistr	L	
	"		27:887-892 (1988)									
	DI		Wu G.Y. et al.; "	Receptor-Med	liated Gene Deli	very and Expression	n in Vivo	; 263:146	521-14624 (1	988)		
	\$ "ES		Wu G Y et al • "	Recentor-Med	liated Gene Deli	very in Vivo"; J. [Riological	Chemistr	v 266:14338	-14342 (1991)	
	DJ											
		Wu G.Y. et al.: "Receptor-Mediated in Vitro Gene Transformation by a Soluble DNA Carrier System";										
	DK		J. Biological Che	<u> </u>								
			Wu G.Y. et al.; "	Targeting Ge	nes:Delivery ar	nd Persistent Expres	ssion of a	Foreign	Gene Driver	by Mamma	alian	
J	DL		Regulatory Elemer	its in Vivo";	J. Biological	<u>Chemistry</u> 264:16985	5-16987 (1	989)				
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Fraser, M.J.; "The baculovirus-infected insect cell as a eukaryotic gene expression system"; Curr. Top.

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93:2348-2352 (1996)

Microbiol. Immunol.; 158:131-172 (1992)

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary) APPLICANT

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OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)

		Trujillo, M.A. et al.; "Functional analysis of a liver-specific enhancer of the hepatitis B virus"; Proc.
BC	L \	Nat'l. Acad. Sci., USA; 88:3797-3801 (1991)
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